

### REMARKS

In response to the Office Action mailed April 23, 2004, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the following comments.

In the Office Action, the Examiner rejected Claims 1-20 on the basis of obviousness-type double patenting over claims 1-13 of U.S. Patent No. 5,587,893 (Luther et al.) in view of Howell (U.S. Pat. 5,830,190). The Applicant respectfully submits that the rejection is improper because none of the '893 claims recite the limitation of a single unitary catheter having an integral distal end that has a harder material than the balance of the catheter. In contrast, the claims of the '893 patent describe a catheter having multiple discrete parts that are assembled to form the claimed catheter; namely, (i) a catheter body, (ii) a rigid, tubular sleeve, and (iii) a distal tip member, each of which is shown by example in the specification as components 46, 54, and 64. Without the "sleeve" claimed in the '893 patent, the "distal tip member" cannot be connected to the main catheter body. In contrast to the '893 claims, Applicant's present application claims a catheter of unitary construction wherein the distal end is integral with, *and not discrete from*, the catheter itself.

Eliminating the interface between the hard and soft material is inventive and valuable. The invention of the present application is not subject to manufacturing complications that result from the construction of a catheter made from multiple parts (3 different parts of the '893 catheter) made of materials of different properties. The manufacturing process of the '893 patent, wherein the annular member (64) is subject to an RF heating process in a frustoconically shaped cavity mold (68), is extremely susceptible to the formation of a "bump" or bulge at the location indicated by 50 in Figure 8. This is a result of the differing temperatures at which the respective materials can be molded, formed, or joined. The formed "bump" causes the patient serious discomfort because the insertion of the catheter into the patient's skin is met with increased resistance. The result is a catheter that is potentially unusable.

The unitary construction of the present invention is not susceptible to the formation of a "bump" at the indicated location, because the distal end is integral with, *and not discrete from*, the catheter itself. The result is a catheter requiring significantly less insertion force to penetrate a patient's skin and vascular system, ultimately resulting in less patient discomfort.

Applicant has enclosed herewith a copy of the Declaration of Nicolaas C. Besseling pursuant to 37 C.F.R. § 1.132 that reflects the advancement provided by the inventive features

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described and claimed in the present application. Given that, the double patenting rejection does not appear warranted. Moreover, the claimed invention is neither anticipated nor obvious over the prior art. No prior art of which Applicant is aware shows the combination of a single unitary catheter having an integral distal end that has a harder material than the balance of the catheter.

In the Final Office Action mailed May 20, 2003 of the abandoned application to which the present application is a continuation, the Examiner responded to the argument by the Applicant that the '893 patent is a much different catheter than the claimed invention and that the distal end is not discrete from the catheter itself, by stating that "it has been held that to make something integral or separate from requires only ordinary skill in the art." The limitation of a single unitary catheter having an integral distal end that has a harder material than the balance of the catheter of the present invention supports a determination of non-obviousness, and cannot be dismissed on the per se rule stated by the Examiner. As stated by the Federal Circuit, "reliance on per se rules of obviousness is legally incorrect and must cease." In re Ochiai, 71 F.3d 1565, 1572, 37 U.S.P.Q.2d 1127, 1133 (Fed. Cir. 1995).

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Conclusion


Applicant has endeavored to address the Examiner's concerns as expressed in the outstanding Office Action. Thus, the Applicant respectfully requests that the Examiner allow the claims as originally filed. If the Examiner finds any remaining impediment to the prompt allowance of the specification and the claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 6/4/04

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AMEND  
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